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CLAIMS

1. A method of selecting an operating parameter value for supplying energy to an ablation electrode, comprising:
 - 5 (a) receiving a first signal representing a value of a fluid flow rate;
 - (b) receiving a second signal representing a value of an impedance;
 - (c) receiving a third signal representing a value of a distance from an ablation electrode surface to a target tissue surface; and
 - (d) selecting a value for an operating parameter for supplying energy to
 - 10 the ablation electrode as a function of the first, second and third signals.
2. The method according to claim 1 wherein (d) comprises selecting the operating parameter value based on relationships established between (1) values of the operating parameter and (2) fluid flow rate values, impedance values and distance
- 15 values.
3. The method according to claim 2, wherein the relationships are established with analyses of a numerical model of transmission of energy to biological tissue by an ablation electrode.
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4. The method according to claim 3 wherein the numerical model comprises a finite element model.
5. The method according to claim 4 wherein, to model a tissue
- 25 temperature distribution, the numerical model comprises equations for modeling an electric field created by the ablation electrode, heat generated by the electric field, and a velocity field of the fluid flow.
6. The method according to claim 5 wherein the numerical model
- 30 comprises the following equations to model tissue temperature distribution:

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$$\nabla \cdot \sigma \nabla \phi = 0 ;$$

$$\rho c \left(\frac{\delta T}{\delta t} + U \frac{\delta T}{\delta x} + V \frac{\delta T}{\delta y} + W \frac{\delta T}{\delta z} \right) = \nabla \cdot (k \nabla T) + J \cdot E ;$$

$$\rho \left(\frac{\delta U}{\delta t} + U \frac{\delta U}{\delta x} + V \frac{\delta U}{\delta y} + W \frac{\delta U}{\delta z} \right) = - \frac{\delta P}{\delta x} + \mu \left(\frac{\partial^2 U}{\partial x^2} + \frac{\partial^2 U}{\partial y^2} + \frac{\partial^2 U}{\partial z^2} \right) ;$$

$$\rho \left(\frac{\delta V}{\delta t} + U \frac{\delta V}{\delta x} + V \frac{\delta V}{\delta y} + W \frac{\delta V}{\delta z} \right) = - \frac{\delta P}{\delta y} + \mu \left(\frac{\partial^2 V}{\partial x^2} + \frac{\partial^2 V}{\partial y^2} + \frac{\partial^2 V}{\partial z^2} \right) ;$$

$$5 \quad \rho \left(\frac{\delta W}{\delta t} + U \frac{\delta W}{\delta x} + V \frac{\delta W}{\delta y} + W \frac{\delta W}{\delta z} \right) = - \frac{\delta P}{\delta z} + \mu \left(\frac{\partial^2 W}{\partial x^2} + \frac{\partial^2 W}{\partial y^2} + \frac{\partial^2 W}{\partial z^2} \right) ; \text{ and}$$

$$\frac{\delta U}{\delta x} + \frac{\delta U}{\delta y} + \frac{\delta U}{\delta z} = 0 .$$

7. The method according to claim 2, wherein the relationships are established with analyses of an *in vitro* model of transmission of energy to biological tissue by an ablation electrode.

8. The method according to claim 1, wherein the second signal, representing the value of the impedance, comprises a signal representing an electrode geometry.

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9. The method according to claim 1, wherein the second signal, representing the value of the impedance, represents an impedance into which energy is supplied.

20 10. The method according to claim 1, wherein (d) comprises selecting a plurality of values for an operating parameter, each value corresponding to a separate time during the supplying of energy to the ablation electrode.

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11. The method according to claim 1, wherein (d) comprises selecting only one value for an operating parameter, the operating parameter to remain constant during the supplying of energy to the ablation electrode.

5 12. The method according to claim 1, wherein (d) comprises selecting a value for each of a plurality of operating parameters.

13. The method according to claim 1, wherein (d) comprises selecting a plurality of values for each of a plurality of operating parameters, wherein for each of
10 the plurality of operating parameters, each value corresponds to a separate time during the supplying of energy to the ablation electrode.

14. The method according to claim 1, wherein the operating parameter is a maximum temperature allowed for the ablation electrode.

15 15. The method according to claim 1, wherein the operating parameter is power applied to the ablation electrode.

16. The method according to claim 1, wherein the operating parameter is
20 voltage of the energy supplied to the ablation electrode.

17. The method according to claim 1, wherein the operating parameter is current supplied to the ablation electrode.

25 18. The method according to claim 1, wherein the operating parameter is a wave shape of the energy supplied to the ablation electrode.

19. The method according to claim 1, wherein the operating parameter is a frequency of the energy supplied to the ablation electrode.

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20. The method according to claim 1, wherein (d) comprises selecting the operating parameter value using a processor programmed with an algorithm.

21. The method according to claim 1, wherein (d) comprises selecting the
5 operating parameter value using an operating curve.

22. The method according to claim 1, wherein (d) comprises selecting the operating parameter value using a lookup table.

10 23. The method according to claim 1, wherein (a) comprises receiving the first signal from a fluid flow sensor.

24. The method according to claim 1, wherein the first signal is generated by an input entered by a user.

15 25. The method according to claim 1, wherein (b) comprises receiving the second signal from an impedance sensor.

26. The method according to claim 1, wherein the second signal is
20 generated by an input entered by a user.

27. The method according to claim 1, wherein (c) comprises receiving the third signal from a distance sensor.

25 28. The method according to claim 1, wherein the third signal is generated by an input entered by a user.

29. The method according to claim 1, wherein the first signal represents a value of a blood flow rate.

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30. A method of supplying energy to an ablation electrode comprising the method of claim 1 and further comprising:

(e) controlling an energy supply such that energy is supplied to the ablation electrode at the selected operating parameter value.

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31. A method of ablating biological tissue to form a lesion comprising:

(a) positioning an ablation electrode having a surface at an ablation site;

(b) receiving a first signal representing a value of a fluid flow rate;

10 (c) receiving a second signal representing a value of an impedance;

(d) receiving a third signal representing a value of a distance from the ablation electrode surface to a target tissue surface;

(e) selecting a value for an ablation operating parameter as a function of the first, second and third signals; and

15 (f) operating the ablation electrode at the selected operating parameter value to ablate biological tissue.

32. The method according to claim 31 wherein the value for the ablation operating parameter selected in (e) is for an energy operating parameter.

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33. The method according to claim 31 wherein the operating parameter is maximum electrode temperature.

34. A system comprising

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a catheter having a shaft;

an ablation electrode positioned on the shaft;

an energy supply;

an input interface configured to receive a signal representing a value of a fluid flow rate, a signal representing a value of an impedance, and a signal representing a value of a distance from an electrode surface to a target tissue surface;

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a processor operatively connected to the input interface and
programmed to select an operating parameter value for supplying energy to the
ablation electrode with the energy supply, the selection being a function of the
three signals received by the input interface; and

5 an output interface operatively connected to the processor and
configured to provide the selected operating parameter value.

35. A computer-readable medium having instructions stored thereon that,
as a result of being executed by a computer, instruct the computer to perform a
10 method comprising:

- (a) receiving a first signal representing a value of a fluid flow rate;
- (b) receiving a second signal representing a value of an impedance;
- (c) receiving a third signal representing a value of a distance from an
ablation electrode surface to a target tissue surface; and
- 15 (d) selecting a value for an operating parameter for supplying energy to
the ablation electrode as a function of the first, second and third signals.

36. A system comprising:

- a catheter having a shaft;
- 20 an ablation electrode positioned on the shaft;
- an energy supply;
- an input interface configured to receive a first signal representing a
value of a fluid flow rate, a second signal representing a value of an
impedance, and a third signal representing a value of a distance from an
25 electrode surface to a target tissue surface;
- means for selecting an operating parameter value for supplying energy
to the ablation electrode with the energy supply, the means for selecting using
the first, second and third signals; and
- an output interface configured to provide the selected operating
30 parameter value.

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37. The system according to claim 36, wherein the operating parameter is maximum electrode temperature.

38. A method of selecting an operating parameter value for transmitting
5 energy to tissue, comprising:

(a) receiving a first signal representing a value of a fluid flow rate near the tissue;

(b) receiving a second signal representing a value of an impedance; and

(c) selecting a value for a distance to set an ablation electrode surface
10 apart from a target tissue surface as a function of the first and second signals.

39. The method according to claim 38, further comprising:

(d) selecting a value for an operating parameter for supplying energy to an ablation electrode.

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40. The method according to claim 39, wherein the operating parameter is a maximum temperature allowed for the ablation electrode.

41. The method according to claim 39, wherein the operating parameter is
20 power applied to the ablation electrode.

42. The method according to claim 39, wherein the operating parameter is voltage of the energy supplied to the ablation electrode.

43. The method according to claim 39, wherein (d) comprises selecting a
25 value for an operating parameter as a function of the first and second signals and the selected distance value.

44. A method of selecting an operating parameter value for transmitting
30 energy to tissue, comprising:

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(a) receiving a first signal representing a value of a fluid flow rate near the tissue; and

(b) selecting a value for a distance to set an ablation electrode surface apart from a target tissue surface as a function of the first signal.

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45. The method according to claim 44, further comprising:

(c) selecting a value for an operating parameter for supplying energy to an ablation electrode.

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46. The method according to claim 45, wherein the operating parameter is a maximum temperature allowed for the ablation electrode.

47. The method according to claim 45, wherein the operating parameter is power applied to the ablation electrode.

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48. The method according to claim 45, wherein the operating parameter is voltage of the energy supplied to the ablation electrode.

49. The method according to claim 45, wherein (c) comprises selecting the value for the operating parameter for supplying energy to the ablation electrode as a function of the first signal and the selected distance value.

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50. The method according to claim 44, wherein (b) comprises selecting the distance based on relationships established between (1) values of the distance and (2) fluid flow rate values.

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51. The method according to claim 50, wherein the relationships are established with analyses of a numerical model of transmission of energy to biological tissue by the ablation electrode.

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52. The method according to claim 51, wherein the numerical model comprises a finite element model.

53. The method according to claim 52 wherein, to model a tissue
5 temperature distribution, the numerical model comprises equations for modeling an electric field created by the ablation electrode, heat generated by the electric field, and a velocity field of the fluid flow.

54. The method according to claim 53 wherein the numerical model
10 comprises the following equations to model tissue temperature distribution:

$$\nabla \cdot \sigma \nabla \varphi = 0 ;$$

$$\rho c \left(\frac{\delta T}{\delta t} + U \frac{\delta T}{\delta x} + V \frac{\delta T}{\delta y} + W \frac{\delta T}{\delta z} \right) = \nabla \cdot (k \nabla T) + J \cdot E ;$$

$$\rho \left(\frac{\delta U}{\delta t} + U \frac{\delta U}{\delta x} + V \frac{\delta U}{\delta y} + W \frac{\delta U}{\delta z} \right) = -\frac{\delta P}{\delta x} + \mu \left(\frac{\partial^2 U}{\partial x^2} + \frac{\partial^2 U}{\partial y^2} + \frac{\partial^2 U}{\partial z^2} \right) ;$$

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$$\rho \left(\frac{\delta V}{\delta t} + U \frac{\delta V}{\delta x} + V \frac{\delta V}{\delta y} + W \frac{\delta V}{\delta z} \right) = -\frac{\delta P}{\delta y} + \mu \left(\frac{\partial^2 V}{\partial x^2} + \frac{\partial^2 V}{\partial y^2} + \frac{\partial^2 V}{\partial z^2} \right) ;$$

$$\rho \left(\frac{\delta W}{\delta t} + U \frac{\delta W}{\delta x} + V \frac{\delta W}{\delta y} + W \frac{\delta W}{\delta z} \right) = -\frac{\delta P}{\delta z} + \mu \left(\frac{\partial^2 W}{\partial x^2} + \frac{\partial^2 W}{\partial y^2} + \frac{\partial^2 W}{\partial z^2} \right) ; \text{ and}$$

$$\frac{\delta U}{\delta x} + \frac{\delta U}{\delta y} + \frac{\delta U}{\delta z} = 0 .$$

55. The method according to claim 50, wherein the relationships are established with analyses of an *in vitro* model of transmission of energy to biological
20 tissue by an ablation electrode.

56. A method of selecting an operating parameter value for supplying energy to an ablation electrode, comprising:

25 (a) receiving a first signal representing a value of a fluid flow rate near the tissue;

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(b) receiving a second signal representing a value of a distance from an ablation electrode surface to a target tissue surface; and

(c) selecting a value for an operating parameter for supplying energy to an ablation electrode as a function of the first and second signals.

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57. The method according to claim 56, further comprising:

(d) receiving a third signal representing a value of an impedance, wherein (c) comprises selecting a value for the operating parameter as a function of the third signal.

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58. A method of selecting an operating parameter value for transmitting energy to tissue, comprising:

(a) receiving a first signal representing a value of a fluid flow rate near the tissue;

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(b) receiving a second signal representing a value of a distance from an ablation electrode surface to a target tissue surface; and

(c) selecting a value for an electrode impedance as a function of the first and second signals.

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59. The method according to claim 58, further comprising:

(d) selecting a value for an operating parameter for supplying energy to an ablation electrode.

60. The method according to claim 59, wherein the operating parameter is a maximum temperature allowed for the ablation electrode.

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61. The method according to claim 59, wherein the operating parameter is power applied to the ablation electrode.

62. The method according to claim 59, wherein the operating parameter is voltage of the energy supplied to the ablation electrode.

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63. The method according to claim 59, wherein (d) comprises selecting a value for an operating parameter as a function of the first signal, the second signal and the selected electrode impedance.

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64. The method according to claim 58, wherein (c) comprises selecting an electrode from a plurality of electrodes.

65. The method according to claim 58, wherein (c) comprises selecting a size for an ablation electrode having an adjustable size.

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66. A method of establishing a relationship between operating condition values and a value for an ablation operating parameter, the method comprising:

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(a) providing a plurality of data sets comprising a value of fluid flow, a value of impedance, and a value of distance from an ablation electrode surface to a target tissue surface;

20

(b) for each of the plurality of data sets, performing at least two analyses of an ablation electrode transmitting energy to biological tissue using a numerical model, the at least two analyses corresponding to at least two different values of an ablation operating parameter, and wherein the numerical model uses each of the three values of the data set; and

(c) based on the results of the at least two analyses for each data set, establishing a relationship between each data set and a corresponding value for the ablation operating parameter.

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67. The method according to claim 66 wherein (c) comprises calculating one of a maximum and a minimum value for the ablation operating parameter at which a maximum tissue temperature does not exceed a pre-selected temperature.

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68. The method according to claim 67, further comprising associating the calculated ablation operating parameter value with the data set.

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69. The method according to claim 67, wherein the pre-selected temperature is approximately 95 degrees Centigrade.

5 70. The method according to claim 66 wherein (c) comprises calculating a value for the operating parameter at which a lesion size is maximized without a maximum tissue temperature exceeding a pre-selected temperature.

71. The method according to claim 70, wherein the pre-selected
10 temperature is approximately 95 degrees Centigrade.

72. The method according to claim 66, wherein the established relationship comprises an equation relating (1) a value of fluid flow, a value of impedance, and a value of distance from an ablation electrode surface to a target tissue surface to (2) an
15 operating parameter value.

73. The method according to claim 66, wherein the established relationship comprises an operating curve.

20 74. The method according to claim 66, wherein the established relationship comprises a lookup table.

75. The method according to claim 66, wherein the numerical model comprises a finite element model.
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76. The method according to claim 66, wherein the at least two analyses comprise at least two computer simulations.

77. The method according to claim 66, wherein the ablation operating
30 parameter is a power level.

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78. The method according to claim 66, wherein the ablation operating parameter is a maximum allowed electrode temperature.

5 79. The method according to claim 66, wherein the ablation operating parameter is a voltage level.

80. The method according to claim 66, further comprising:

10 (d) performing a plurality of model analyses using different values for impedance and distance from an ablation electrode surface to a target tissue surface; and

(e) assigning a value for the operating parameter, a value for the distance, and a value for the impedance to the value for the fluid flow based on results of the model analyses.

15 81. The method according to claim 80, wherein (e) comprises optimizing the operating parameter value, the impedance value and the distance value for a maximum predicted lesion size without the model analysis indicating a tissue temperature exceeding a pre-selected temperature.

20 82. The method according to claim 81, wherein the pre-selected temperature is approximately 95 degrees centigrade.

25 83. The method according to claim 80, wherein assigning a value for the impedance comprises assigning an electrode geometry selected from a plurality of electrode geometries.

84. The method according to claim 66, wherein the numerical model comprises a finite element model.

30 85. The method according to claim 66 wherein, to model a tissue temperature distribution, the numerical model comprises equations for modeling an

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electric field created by the ablation electrode, heat generated by the electric field, and a velocity field of the fluid flow.

86. The method according to claim 85 wherein the numerical model
5 comprises the following equations to model temperature distribution:

$$\begin{aligned} \nabla \cdot \sigma \nabla \varphi &= 0 ; \\ \rho c \left(\frac{\delta T}{\delta t} + U \frac{\delta T}{\delta x} + V \frac{\delta T}{\delta y} + W \frac{\delta T}{\delta z} \right) &= \nabla \cdot (k \nabla T) + J \cdot E ; \\ \rho \left(\frac{\delta U}{\delta t} + U \frac{\delta U}{\delta x} + V \frac{\delta U}{\delta y} + W \frac{\delta U}{\delta z} \right) &= -\frac{\delta P}{\delta x} + \mu \left(\frac{\partial^2 U}{\partial x^2} + \frac{\partial^2 U}{\partial y^2} + \frac{\partial^2 U}{\partial z^2} \right) ; \\ 10 \quad \rho \left(\frac{\delta V}{\delta t} + U \frac{\delta V}{\delta x} + V \frac{\delta V}{\delta y} + W \frac{\delta V}{\delta z} \right) &= -\frac{\delta P}{\delta y} + \mu \left(\frac{\partial^2 V}{\partial x^2} + \frac{\partial^2 V}{\partial y^2} + \frac{\partial^2 V}{\partial z^2} \right) ; \\ \rho \left(\frac{\delta W}{\delta t} + U \frac{\delta W}{\delta x} + V \frac{\delta W}{\delta y} + W \frac{\delta W}{\delta z} \right) &= -\frac{\delta P}{\delta z} + \mu \left(\frac{\partial^2 W}{\partial x^2} + \frac{\partial^2 W}{\partial y^2} + \frac{\partial^2 W}{\partial z^2} \right) ; \text{ and} \\ \frac{\delta U}{\delta x} + \frac{\delta U}{\delta y} + \frac{\delta U}{\delta z} &= 0 . \end{aligned}$$

87. A method of establishing a relationship between operating condition
15 values and values for ablation operating parameters, the method comprising:

- (a) providing a data set comprising values of operating conditions;
- (b) performing a first analysis of a numerical model, the numerical model modeling transmission of energy to biological tissue, the first analysis using the values of the operating conditions, a first value for an energy supply
20 operating parameter and a first value for a distance from an ablation electrode surface to a target tissue surface;
- (c) performing a second analysis of the numerical model using the values of the operating conditions and a second value for the distance from the ablation electrode surface to the target tissue surface; and
- 25 (d) based on the results of the first and second analyses, establishing a relationship between the data set and corresponding values for the energy

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supply operating parameter and the distance from the ablation electrode surface to the target tissue surface.

88. The method according to claim 87, wherein (d) comprises performing
5 the second analysis using a second value for the energy operating parameter.

89. The method according to 88, further comprising performing a plurality of additional analyses using the values of the operating conditions and additional values for the energy supply operating parameter and the distance from the ablation
10 electrode surface to the target tissue surface.

90. The method according to claim 89, wherein the energy supply operating parameter is maximum electrode temperature.